

REMARKS

Claims 1-15 are currently pending in this application. Applicants respectfully request favorable consideration of the present application in light of the amendments to the claims and the following remarks.

I. Claims

A. 35 USC 112, 1st Paragraph

In Paragraph 5 of the Office Action, Claims 1 and 11 were rejected under 35 USC 112, 1st Paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), as the time the application was filed, had possession of the invention.

The legal test for satisfaction of 35 USC Section 112, 1st Paragraph, is that one skilled in the art must be able to practice the invention without undue experimentation. *Utter v. Hiraga*, 845 F.2d 993, 6 USPQ.2d 1709 (Fed. Cir. 1988). Applicants respectfully submit that the specification contains disclosure sufficient to enable one of ordinary skill in the art to practice the claimed invention (of previously amended claims 1 and 11) without undue experimentation.

Claim 1, as currently amended, recites:

“1. (Currently Amended) A composition for filling a void in an orthopedic joint or between bone separations, the composition comprising:

a polymeric matrix selected from a group consisting of gutta percha, balata, and polyisoprene, and any mixtures thereof; and

a dispersion phase *disposed at least partially within the polymeric matrix*^{*}, the dispersion phase comprising titanium particles less than 50 microns in size;

the composition having a resilient, non-dispersing state at or below body temperature, and heatable to a fluid state above body temperature, such that the composition is injectable into the void *while in the fluid state*^{*}, thereafter returning to the resilient, non-dispersing state.”

Claim 11, as currently amended, recites:

11. (Currently Amended) A composition for filling a void of an orthopedic joint or between bone separations, the composition having a resilient, non-dispersing state at body temperature, and heatable to a fluid state for injection into the void, the composition comprising:

a polymeric matrix selected from a group consisting of gutta percha, balata, and polyisoprene, and any mixtures thereof; and

titanium particles less than 50 microns in size, the titanium particles comprising between 1 and 50 percent by weight of the composition;

the composition having a resilient, non-dispersing state at or below body temperature, and heatable to a fluid state above body temperature, such that the composition is injectable into the void *while in the fluid state*^{*}, thereafter returning to the resilient, non-dispersing state.

* Claim limitations believed to have precipitated the rejection under 35 USC 112, 1st Paragraph.

With respect to the claim language “**a dispersion phase *disposed at least partially within the polymeric matrix***” of Claim 1, Applicants respectfully submit that the added claim language is supported in at least the following portions of the specification:

Location in Spec	Support	Significance
Page 4, Lines 6-7	“The preferred embodiment is a composite material, including a polymer matrix, such as gutta percha, and a dispersion phase, such as titanium particles.”	Teaches “dispersion phase” and “polymeric matrix”
Page 10, Lines 10-12	“A [titanium] particle size may be chosen small enough that the resulting composition 10 may be a molecular mixture, with favorable properties inherent thereto, such as superior mixability with the polymer matrix.”	Teaches that “dispersion phase” is <u>mixed</u> with the “polymeric matrix” to form the claimed composition.
Figures 1 and 2	Illustration of titanium particles 14 (FIG. 1) and titanium “whiskers” 24 (FIG. 2) exposed to the exterior of the polymer matrix 12, 22.	Teaches that “dispersion phase” may be disposed at least partially within the “polymeric matrix.”

With regard to the claim language “**the composition is injectable into the void *while in the fluid state***” of Claims 1 and 11, Applicants respectfully submit that the added claim language is supported in at least the following portions of the specification:

Location in Spec	Support	Significance
Page 9, Lines 4-8	“The matrix 12 has a resilient, non-dispersing, solid state at body temperature, and may be heated to a fluid state above body temperature. The matrix 12 is thermoplastic polymer, such that when cooled to body temperature it returns to the solid state with original solid-state mechanical properties.”	Teaches that the composition (comprising the “dispersion phase” and the “polymeric matrix”) has a fluid state above body temperature.
Page 11, Line 20 – Page 12, Line 6	“When needed, the composition 10 may be reheated to its liquid form from within the compressible tube 30, such as by placing in	Teaches that the claimed composition is injected into the void while in the fluid

	an oven, in hot water, or over an open flame. The composition 10 may then be squeezed from the compressible tube 30, through the nozzle 34, by applying force to the tube wall 32. The force may be applied to the tube wall 32 either by hand or through mechanical means, such as by using a spring-biased roller 38. The compressible tube 30 may also facilitate the filling the void [sic] by transporting the composition 10 into the void."	state.
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Based on the above-identified charts, Applicants respectfully submit that the subject matter of Claims 1 and 11 *are* described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), as the time the application was filed, had possession of the invention. As such, Applicants respectfully request that the rejection of claims 1 and 11 under 35 USC 112, 1st Paragraph, be withdrawn in favor of an indication of allowance.

B. 35 USC 103(a) – Mannschedel in view of Shoher et al.

In Paragraph 7 of the Office Action, Claims 1-15 were rejected as being unpatentable over US Pat. No. 6,126,446 to Mannschedel ("Mannschedel") in view of U.S. Pat. No. 5,272,184 to Shoher et al. ("Shoher"). In Paragraph 8 of the Office Action, the Examiner went on to assert that the arguments submitted in Paper No. 5 (received on Nov. 27, 2002) were not persuasive "because the instant claims are directed to a composition and not to a process" and because the "prior art teaches the ingredients which make the claimed composition." Applicants respectfully traverse this rejection as follows.

While the instant claims are drawn to a composition (as opposed to a process), the claimed composition has very specific characteristics – which importantly are nowhere to be found or suggested in the cited or known prior art. Namely, the claimed composition has the characteristic of being “injectable into the void while in the fluid state.” While Mannschedel does disclose a composition including gutta percha, the gutta percha described therein is provided as a powder which is *not* injectable into the void while in the fluid state above body temperature. Instead, the gutta percha powder is simply combined with a sealer and thereafter introduced into the root canal. Given this void, it necessarily follows that the gutta percha of Mannschedel is not “injectable into the void while in the fluid state (above body temperature), as set forth in amended claims 1 or 11.

While Shoher does disclose the use of metals such as titanium for filling a dental cavity, it nonetheless teaches away from any combination with a flowable composition such as the polymeric matrix of the present invention. The metallic composition of Shoher is first introduced into the dental cavity while in a “putty-like” form such that it will “readily assume the geometry of the cavity (8) with minimal pressure.” (Col. 4, lines 45-47). There is no teaching whatsoever that the putty-like metallic composition is heated prior to introduction. The metallic composition (in putty form and non-elevated temperature) is then removed from the dental cavity and *thereafter* heat-treated to form a porous metal structure (Col. 4, lines 66-67). This heat-treating occurs outside the dental cavity. Only after this heat-treating can the dental implant of Shoher be re-introduced into the dental cavity (Col. 6, lines 47-50).

The thermopolymer composition of the present invention, on the other hand, is specifically comprised to be injectable into a void while in the fluid state due to being heated above body temperature. Shohar appears to be completely silent regarding any such teaching. This is a significant distinction in that the process of Shohar will necessarily take a considerable amount of time to fill a dental cavity with the metallic composite, based on the need to initially fit the dental cavity, remove the composite, heat the composite to provide a metal structure, and re-introduce the structure into the dental cavity. The thermopolymer composition of the present invention, on the other hand, is capable of quickly and easily filling voids by raising the temperature until it assumes a flowable fluid state, injecting it into the particular void to be filled, and allowing it to cool such that it can assume a resilient, non-dispersing form within the void.

Based on the foregoing, Applicants respectfully submit that the Mannschedel and Shohar references, whether taken alone or in combination, fail to contain the requisite teaching or suggestion that would have lead one of ordinary skill in the art to the present invention as set forth in amended claims 1 and 11. It is respectfully requested that the rejection in Paragraph 7 of the Office Action be withdrawn. Claims 1 and 11 are believed to be in proper condition for allowance and an indication of such is hereby respectfully requested.

Claims 2-10 and 12-15, being dependent upon and further limiting independent claims 1 and 11, respectively, should be allowable for the reasons set forth in support of the allowability of claims 1 and 11, as well as the additional limitations they contain.

CONCLUSION

Reconsideration and allowance of the claims in this application is respectfully requested.

In the event that there are any questions concerning the remarks above or the application in general, the Examiner is cordially invited to telephone the undersigned attorney so that prosecution may be expedited.

Respectfully submitted,
NUVASIVE, INC.

By: 

Jonathan Spangler, Esq.
Registration No. 40,182

10065 Old Grove Road
San Diego, CA 92131
Tel.: (858) 243-0029

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